

## REMARKS

Claims 30-59 are presently pending in this application. In the present Amendment, Applicants have cancelled claims 31-34 and 40-42 and amended claims 30, 44-46, 53 and 59. Therefore, claims 30, 35-39 and 43-59 are under consideration. No new matter was added to the application by way of the present Amendment.

### Priority Claim

Applicants note that the Examiner has acknowledged and accepted Applicants' claim for priority based on prior application PCT/EP00/01144, filed on February 11, 2000, and also based on the prior application filed in Switzerland on February 11, 1999. Applicants provide herewith a certified copy of the Swiss provisional application in accordance with 35 U.S.C. 119(b).

### Claim Objections

The Examiner objected to the use of roman numerals in the claim subparts of claims 44 and 53 as being "inconsistent," because other claims in the application use lower case letters for the claim subparts. Applicants have amended claims 44 and 53, and dependent claims 45 and 46, so that the claim subparts are referenced using lower case letters. Accordingly, Applicants respectfully submit that the Examiner's rejection has been overcome.

The Examiner also objected to claim 53 as being in improper dependent form for failing to limit the subject matter of a previous claim. Applicants have amended subpart (a) (previously subpart "(i)") of claim 53 to recite "the heat inducible promoter." Accordingly, Applicants respectfully submit that the Examiner's objection has been overcome.

### Rejection of Claim 59 under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claim 59 under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, it is the Examiner's view that claim 59 claims "a method," but does not set forth any steps comprising the claimed method.

Applicants have amended claim 59 herein to properly recite method steps. Specifically, claim 59 has been amended to recite the method of original claim 28. Original claim 28 depends from claim 22, which encompasses an expression vector comprising a nucleic acid molecule of claim 8, which claim is drawn to a nucleic acid comprising a heat shock element of the invention, and in particular, SEQ ID NO:4 or SEQ ID NO:5.

In comparison, Applicants direct the Examiner's attention to claim 37, from which presently amended claim 59 depends. Claim 37 is also drawn to a nucleic acid comprising SEQ ID NO:4 or SEQ ID NO:5. Applicants respectfully submit that the subject matter of amended claim 59 was indeed in the present application at the time of filing, and therefore, the amendments to claim 59 do not introduce new matter into the present application. Accordingly, Applicants respectfully submit that the Examiner's indefiniteness rejection of claim 59 is not applicable in light of the amendments to claim 59 set forth herein, and respectfully request withdrawal of the rejection.

#### Rejection of Claims 30-59 under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 30-59 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed (a "written description" rejection). In particular, the Examiner rejects the claim language drawn to fragments, variants, and homologs of heat inducible promoters of the present invention because, in the Examiner's view, the specification does not provide "a representative number of species sufficient to convince the skilled artisan that the applicant is in possession of the claimed genus."

While not necessarily agreeing with the Examiner's reasoning, Applicants have canceled claims 31-34, rendering the Examiner's rejection of those claims moot. Applicants have also cancelled claims 40-42 and incorporated the subject matter of those claims into claim 30 by way of the amendments described herein, rendering the Examiner's rejection of claims 40-42 moot.

Further, Applicants have amended claim 30 herein to remove all language directed to non-specific fragments, variants and homologs of SEQ ID NO:1. Specifically, Applicants have deleted claim language directed to “40 percent identity,” as well as language directed to “derivatives” of SEQ ID NO:1. Further, Applicants have amended subpart (f) of claim 30 so that subpart (f) is drawn only to three specific fragments of SEQ ID NO:1, and subpart (f) further requires that such fragments must have the functional activity of a heat-inducible promoter of the present invention. Applicants respectfully submit that the functional language in claim 30 will be understood by one of skill in the art to demonstrate Applicants’ possession of the present invention at the time of filing, as such functional language, taken in conjunction with the sequence of a heat inducible promoter of the claimed invention set forth in SEQ ID NO:1, is evidence of sufficient identifying characteristics of the present invention.

Support for the amendments to claim 30 is found on page 3 of the specification, which includes a definition of “heat inducible promoter.” Applicants also direct the Examiner’s attention to page 2 of the specification, and therein to the second full paragraph beginning with “The object of the invention...,” which defines a heat-inducible promoter of the invention to be active in fungi and yeast, and to be suitable for protein expression at high temperatures. Because the amendments to claim 30 are fully supported in the specification as filed, the amendments to claim 30 therefore add no new matter.

It is apparently the Examiner’s view that the disclosure only provides a “single species” that satisfies the written description requirement, namely, nucleotides 228-792 of SEQ ID NO:1. Applicants respectfully disagree. Applicants have provided written description for the sequence from nucleotide 228 to nucleotide 792 in SEQ ID NO:1, the sequence from nucleotide 492 to nucleotide 792 in SEQ ID NO:1, and the sequence from nucleotide 627 to nucleotide 713 in SEQ ID NO:1, as well as SEQ ID NO:1 in its entirety. As acknowledged by the Examiner on page four of the Office Action, SEQ ID NO:1 represents the entire promoter element.

In any event, Applicants respectfully remind the Examiner that the written description requirement may be satisfied by the presentation of a “representative number of species” of a genus, and that a representative number of species can be a **single** species

where the skill in the relevant art and the predictability of the art is adequate. (Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1, “Written Description” Requirement, Federal Register, Vol. 66, No. 4, Friday, January 5, 2001, page 1106). Satisfactory disclosure of a “representative number” depends on whether one of skill in the art would recognize that the applicant was in possession of the *necessary common attributes or features* of the elements possessed by the members of the genus in view of the species disclosed. (Id.). Applicants submit that a common feature of the limited number of polynucleotides set forth in amended claim 30 is the property of such polynucleotides to function as a heat inducible promoter.

Applicants have set forth both the use and the biological activity of a polynucleotide of the present invention, namely, nucleotides 228-792 of SEQ ID NO:1, and specifically described both aspects in Experimental Examples 3 and 4 in the present application. Applicants respectfully submit that one of ordinary skill in the art would recognize SEQ ID NO:1 in its entirety to contain nucleotides 228-792 of SEQ ID NO:1. One of skill in the art would also recognize that the sequence from nucleotide 492 to nucleotide 792 in SEQ ID NO:1 and the sequence from nucleotide 627 to nucleotide 713 in SEQ ID NO:1 are contained within SEQ ID NO:1, as well as a polynucleotide comprised of nucleotides 228-792 of SEQ ID NO:1. In conjunction with the functional activity of nucleotides 228-792 of SEQ ID NO:1 described above, Applicants respectfully submit that the skilled artisan would consider nucleotides 228-792 of SEQ ID NO:1 to be representative of the genus further comprising the sequence from nucleotide 492 to nucleotide 792 in SEQ ID NO:1, and the sequence from nucleotide 627 to nucleotide 713 in SEQ ID NO:1, as well as SEQ ID NO:1 in its entirety.

Further still, Applicants submit that one of ordinary skill in the art would understand Applicants to be in possession of any one of the species encompassed by amended claim 30, as the skilled artisan would necessarily understand a polynucleotide of the invention (as claimed in claim 30) to necessarily have the biological activity of a heat inducible promoter. Accordingly, one of ordinary skill in the art would understand the polynucleotides encompassed by amended claim 30 to comprise the relevant genus of “heat inducible promoter” polynucleotides of the present invention.

Therefore, Applicants submit that amended claim 30, and remaining claims 35-39 and 43-59, which depend either directly or indirectly from claim 30, satisfy the written description requirement. Accordingly, Applicants respectfully submit that the Examiner's written description rejection has either been overcome or no longer applies, and request reconsideration and withdrawal of the rejection.

#### Rejection Under 35 U.S.C. § 102(a)

The Examiner rejected claims 30-42, 44, 47-49, 51-54 and 56-59 under 35 U.S.C. § 102(a) as being anticipated by Reinders et al. (J. Bacteriology, August 3, 1999, 181:4665-4668). The Examiner's rejection is predicated on the August 3, 1999 publication date of Reinders.

Applicants respectfully disagree, and point out that the present invention properly claims priority of the February 11, 1999 Swiss provisional application, as acknowledged by the Examiner. Applicants have provided a certified copy of the priority document herewith in accordance with 35 U.S.C. 119(b), and accordingly, respectfully submit that the Examiner's anticipation rejection based on the Reinders publication is improper.

Applicants have canceled claims 31-34, rendering the Examiner's rejection of those claims moot. Applicants have also cancelled claims 40-42 and incorporated the subject matter of those claims into claim 30 by way of the amendments described herein, rendering the Examiner's rejection of claims 40-42 moot.

Applicants further note that the Examiner has acknowledged, on page seven of the Office Action, that a proper priority claim to the February 11, 1999 priority document would obviate the present anticipation rejection. Applicants submit that they have indeed established a proper priority claim, and therefore respectfully request withdrawal of the rejection.

#### Rejection Under 35 U.S.C. § 102(b)

The Examiner rejected claims 30, 47-49 and 51-53 under 35 U.S.C. § 102(b), as being anticipated by Xiao-Dong et al. ("the Liu reference"). The Examiner's

rejection appears to be based on subsection (e) of claim 30, which is drawn to “any derivative” of a heat shock promoter of the invention.

While not necessarily agreeing with the Examiner’s reasoning, Applicants have canceled claims 31-34, rendering the Examiner’s rejection of those claims moot. Applicants have also cancelled claims 40-42 and incorporated the subject matter of those claims into claim 30 by way of the amendments described herein, rendering the Examiner’s rejection of claims 40-42 moot.

It is well settled that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP §2131 (quoting *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). “The identical invention must be shown in as complete detail as is contained in the . . . claim.” *Id.* (quoting *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). Therefore, in order for a rejection under 35 U.S.C. § 102(b) to be proper, each and every element of Applicants’ invention must be disclosed by the Xiao-Dong reference. However, the Xiao-Dong reference does not disclose any of the nucleic acids encompassed by amended claim 30, nor does it even disclose nucleic acids sharing any significant homology with SEQ ID NO:1. Specifically, the Xiao-Dong reference does not disclose SEQ ID NO:1, nor does the reference disclose a nucleic acid complementary to SEQ ID NO:1. Further, the Xiao-Dong reference does not disclose any fragment of SEQ ID NO:1 selected from the group consisting of the sequence from nucleotide 228 to nucleotide 792 in SEQ ID NO:1, the sequence from nucleotide 492 to nucleotide 792 in SEQ ID NO:1, and the sequence from nucleotide 627 to nucleotide 713 in SEQ ID NO:1.

As discussed above, Applicants have amended claim 30 to delete subsection (e). Applicants have also amended claim 30 herein to remove all language directed to non-specific fragments, variants and homologs of SEQ ID NO:1. Specifically, Applicants have deleted claim language directed to “percent identity,” as well as language directed to “derivatives” of SEQ ID NO:1. Further, Applicants have amended subpart (f) of claim 30 so that subpart (f) is drawn only to three specific fragments of SEQ ID NO:1, and subpart (f) further requires that such fragments must have the functional activity of a heat-inducible promoter of the present invention.

Therefore, Applicants submit that Xiao-Dong does not anticipate amended claim 30, nor does it anticipate claims 47-49 and 51-53, which depend from claim 30. Accordingly, Applicants respectfully submit that the Examiner's rejection under 35 U.S.C. § 102(b) no longer applies, and respectfully request reconsideration and withdrawal of the invention.

Summary

Applicants respectfully submit that each of the Examiner's objections and rejections has either been overcome or rendered moot, and that each of claims 30, 35-39, and 43-59 is fully supported by the specification as originally filed and in condition for allowance. Consideration and allowance of each of these claims are respectfully requested at the earliest possible date.

Respectfully submitted,

**ROMANO ET AL.**

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(Date)

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